APPENDIX B

MAY 16 2007

510(k) PREMARKET NOTIFICATION SUMMARY

(per 21 CFR 807.92)

THOR VR Single Diode Laser Treatment Probe

I. Applicant:

THOR International Ltd.
18a East Street
Chesham
HP5 1HQ
United Kingdom

Date Prepared: December 21, 2006

II. Device Name

Proprietary Name:	THOR VR Single Diode Laser Treatment Probe
Common / Usual Name:	Therapeutic VR Single Diode Laser Treatment Probe
Classification Name:	Infrared Lamp (21 CFR 890.5500)
Product Code:	ILY

III. Intended Use of the Device

The THOR VR Single Diode Laser Treatment Probe is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or temporary relaxation of muscles.

IV. Predicate Devices

Predicate devices to the THOR VR Diode Probe are the THOR Infrared and Visible Diode Probes (K033923). These devices were cleared for introduction into interstate commerce via the FDA's 510(k) Notification process.

V. Description of the Device

The THOR VR Single Diode Laser Treatment Probe is non-invasive, easy to use, hand-held therapeutic device providing continuous heat therapy. The System is comprised of a Control Unit that houses the electronics and controls the

handheld treatment probe, which delivers infrared energy. The probes are intended to be placed directly on the skin to provide heating.

VI. Summary of the technical characteristics of the THOR VR Single Diode Laser Treatment Probe to the referenced predicate devices

The THOR VR Single Diode Laser Treatment Probe and the aforementioned predicate devices are infrared lamps as defined in 21 CFR 890.5500. These devices utilize infrared and visible laser diodes to generate topical heating for the purpose of elevating tissue temperatures for temporary relief of muscle and joint pain.

VII. Testing

Testing of the THOR VR Single Diode Laser Treatment Probe will include functional performance testing and electrical safety testing in accordance with all applicable standards for this type medical device.

VIII. Conclusions

Pursuant to the testing and comparison to the predicate devices, the THOR VR Single Diode Laser Treatment Probe has the same intended uses, with similar functional and performance characteristics. The System is designed to comply with the generally accepted therapeutic heat performance specifications by producing a level of tissue temperature reported in literature and accepted by the Federal Food and Drug Administration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2007

Thor International, Ltd.
% Texas Applied Biomedical Services
Ms. M. Joyce Heinrich
Regulatory Consultant
12101 Cullen Boulevard, Suite A
Houston, Texas 77047

Re: K070024
Trade/Device Name: THOR VR Single Diode Laser Treatment Probe
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: March 22, 2007
Received: March 27, 2007

Dear Ms. Heinrich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

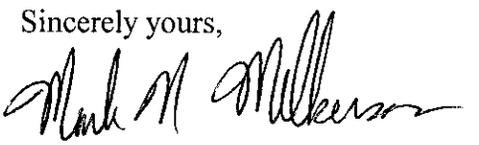
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX C

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K070024

Device Name:

THOR VR Single Diode Laser Treatment Probe

Indications for Use:

The THOR VR Single Diode Laser Treatment Probe is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or temporary relaxation of muscles.

Prescription Use: _X____ **AND/OR** **Over the Counter Use: _____**
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODpE)

Mark N Milhern

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number 510(k) # K070024